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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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EXAMINER

NELSON, A

| ART UNIT | PAPER NUMBER |
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1638

DATE MAILED:

11/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/142,108

Applicant(s)
Fillippa Bugliera, et al.

Examiner
Amy Nelson

Group Art Unit
1638



☒ Responsive to communication(s) filed on Sep 25, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-39 is/are pending in the application.

Of the above, claim(s) 25 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-24 and 26-39 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Sequence Rules

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Specifically, the sequences at page 20, lines 11, 12, and 14, and the sequences in Table 7 do not comply. Applicant must submit a new CRF and paper copy of the Sequence Listing, along with a statement that the two copies are the same and include no new matter.

Full compliance with the Sequence Rules is required in response to this Official action. A complete response to this Official action should include both compliance with the Sequence Rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Official action will be held to be non-responsive.

Election/Restriction

2. Applicant's election with traverse of Group I, Claims 1-24, and 26-39, in Paper No. 15, filed 9/25/00, is acknowledged. The traversal is on the ground(s) that the inventions of Group I and Group II are closely related to each other and represent a single inventive concept. Specifically, Applicant asserts that the coding nucleic acids of Group I and the oligonucleotides of Group II are similarly claimed by their percent similarity or ability to hybridize to specific SEQ ID NO:s (response,

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p. 3). This is not found persuasive because a coding nucleic acid and an oligonucleotide is a distinct invention, differing in composition, structure and function, and requiring different searches and considerations for examination. The invention of Group I, consisting of coding DNAs, constructs, transgenic plants, and transformation methods, as broadly claimed, is disclosed in the prior art (see cited Davies reference). Therefore, there is no special technical feature which links the invention of Group I with that of Group II.

Further, Applicant asserts that excessive costs would be incurred by Applicant due to the restriction requirement, and that a restriction requirement does not insulate Applicant from a double patenting rejection against a child application (response p. 3-5). Examiner responds that excessive costs would be required for examination of multiple inventions, and that cost is not a consideration in restriction practice. Restriction requirement and Double Patenting are indeed separate issues. The issue under consideration here is whether or not Applicant has claimed multiple inventions. For the reasoning discussed above and in the last Official action, it is deemed that restriction is appropriate.

The requirement is still deemed proper and is therefore made FINAL.

3. Claim 25 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. The Van Tunen reference in the Information Disclosure Statement filed 11/23/99 has been considered, but will not be published on the face of the patent because it is an incomplete citation and lacks the publication date. If Applicant would like the reference to be published on the face of the patent, Applicant should resubmit the reference in a Supplemental Information Disclosure Statement with the complete citation, including the publication date.

Specification

7. This application is informal in the arrangement of the specification. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).

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- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Summary of the Invention.
- (g) Brief Description of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Applicant must amend the Specification to insert the Appropriate Section Headings.

8. The material of Table 7 is inappropriate for a table. Table 7 should be deleted from the specification, and resubmitted as an additional Drawing. Tables 8-12 should be renumbered and the Brief Description of Drawings should be amended accordingly.

Claim Objections

9. Claims 2-24, 29, 30, 32, and 34-37 are objected to because of the following informalities:

At Claims 2-24, line 1, "An isolated nucleic acid molecule" should be changed to --The isolated nucleic acid molecule-- because it refers to a previous claim.

At Claims 29, 30, and 32, line 1, "A method" should be changed to --The method-- because it refers to a previous claim.

At Claims 34-37, "a transgenic plant" should be changed to --the transgenic plant-- because
-----it-refers-to-a-previous-claim.-----

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Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-24, and 26-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn broadly toward a nucleic acid molecule encoding a flavonoid 3'-hydroxylase (F3'H) or a derivative thereof which modulates more efficient hydroxylation of flavonoid compounds than SEQ ID NO:26, or a nucleic acid molecule which hybridizes with or has at least 60% similarity to the disclosed nucleic acid molecules or encodes an amino acid sequence with at least 50% similarity to the disclosed amino acid sequence. Applicant describes a nucleic acid molecules from a variety of different ornamental plants with sequence similarity to other F3'H nucleic acid molecules, and shows that at least some of them encode enzymes with flavonoid hydroxylase activity. Applicant does not describe the composition or structure of any nucleic acid molecules which encode enzymes which modulate more efficient hydroxylation than SEQ ID NO:26, and Applicant does not describe nucleic acid molecules encompassed by the broad genus of derivatives, and nucleic acid molecules with sequence similarity or which hybridize with the disclosed nucleic acid molecules,

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and hence it is not clear from the instant specification that the Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

12. Claims 1-24, and 26-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to an isolated nucleic acid molecule encoding a plant F3'H, a gene construct and transgenic plant comprising said nucleic acid molecule, and a method for altering F3'H activity and flower color in transgenic plants with said nucleic acid molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims are indefinite for the reasons described below. However, it appears that Applicant intends to broadly claim a nucleic acid molecule encoding a F3'H or a derivative thereof which modulates more efficient hydroxylation of flavonoid compounds than SEQ ID NO:26, or a nucleic acid molecule which hybridizes with or has at least 60% similarity to the disclosed nucleic acid molecules or encodes an amino acid sequence with at least 50% similarity to the disclosed amino acid sequences. Applicant also claims a gene construct and transgenic plant comprising said nucleic acid

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molecule, and a method for altering F3'H activity and flower color in transgenic plants with said nucleic acid molecule.

Applicant teaches isolation of a F3'H cDNA from petunia by screening a petal cDNA library with cytochrome P450 DNA probes, and teaches that the isolated cDNA is linked to the Ht1 locus and produces an enzyme with F3'H activity when overexpressed in yeast (Examples 3-7; SEQ ID NO:1; encodes SEQ ID NO:2). Applicant teaches that when the cDNA is transiently expressed in petunia petals red anthocyanin spots are observed, and when the cDNA is stably expressed in petunia altered flower (petal, anther, pollen) color and increased production of flavonoids (peonidin, cyanadin and quercitin) results. Applicant also teaches isolation of a F3'H cDNA from carnation, *Arabidopsis*, rose and *Tourenia* by screening a petal cDNA library with the petunia cDNA (Examples 12-14, 22-27, and 29-30; SEQ ID NO:3, 7, 14, 18; encodes SEQ ID NO:4, 8, 15, 19) and from snapdragon by differential display (Examples 15-21; SEQ ID NO:5; encodes SEQ ID NO:6), and definitively shows that each of the cDNAs encodes an enzyme with F3'H activity and/or which alters flower color in transformed plants. Applicant also teaches isolation of putative full length or partial length F3'H cDNAs from chrysanthemum, Japanese morning glory, *Gentiana*, and *lisianthus* (Examples 28, and 31-33; SEQ ID NO:16, 20, 22, 24; encodes SEQ ID NO:17, 21, 23, 25).

Applicant does not teach that any of the isolated cDNAs encode a F3'H with more efficient hydroxylation activity than that of SEQ ID NO:26. Also, Applicant does not teach derivatives of the disclosed nucleic acid molecules, or nucleic acid molecules with at least 60% similarity or which hybridize under low stringency conditions.

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In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The state of the art for isolation of cDNA or genomic clones with a defined functionality, and particularly with increased activity, is highly unpredictable. Significant guidance is required with regard to hybridization/wash conditions and/or PCR conditions that will allow specific isolation of the target genes. Applicant has characterized and isolated several plant cDNAs which definitively encode F3'H, and several putative full length and partial length cDNAs. Applicant has not demonstrated that any of the disclosed DNAs encode an enzyme with more efficient hydroxylation activity as compared to SEQ ID NO:26, and Applicant has not provided guidance for modification of any of the DNAs to achieve more efficient activity. Moreover, Applicant has provided no guidance with respect to what hybridization/wash conditions or what PCR reaction conditions would allow specific isolation of additional functionally related genes, including derivatives, nucleic acid molecules with at least 60% similarity, and nucleic acid molecules which hybridize under low stringency conditions, which likewise encode F3'H or another enzyme with flavonoid hydroxylation activity, particularly with more efficient hydroxylation activity than SEQ ID NO:26. In the absence of such guidance, undue trial and error experimentation would be required to screen through and/or to modify

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the vast number of cDNA and genomic clones from plants or other organisms, to identify those that encode F3'H with increased hydroxylation activity as compared to SEQ ID NO:26.

In particular, Applicant has provided no guidance for the full length or partial length putative F3'H cDNAs from chrysanthemum, Japanese morning glory, Gentiana, and lisianthus (SEQ ID NO:16, 20, 22, 24; encodes SEQ ID NO:17, 21, 23, 25), and has provided no evidence of any hydroxylation activity, much less more efficient activity, of the encoded protein.

Furthermore, Applicant has provided no guidance for vectors, transgenic plants, and methods for altering F3'H activity or altering flower color in transgenic plants with the nucleic acid molecules as so broadly claimed. The nucleic acid molecules as broadly claimed encompass nucleic acid molecules that do not encode F3'H or which encode another enzyme with flavonoid hydroxylase activity. In view of the unpredictability of phenotype in transformed plants, and the limited guidance in the specification directed only to plants transformed with a plant F3'H nucleic acid molecule, it is not clear that plants with altered F3'H activity and altered flower color could be attained by transformation with the all of the nucleic acid molecules as broadly claimed. Hence, it is submitted that the transgenic plants and methods of modifying phenotype in transgenic plants are not enabled throughout the broad scope of the claims.

When the *Wands* factors are weighed it is concluded that undue experimentation would be required to practice the invention throughout the full scope of the claims, and therefore the invention is not enabled.

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13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-24, and 26-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 1, lines 2 and 3, the term “derivative” is indefinite. There are many different types of derivatives, and it is unclear what is encompassed by the term. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claim 1, line 3, “is capable of more efficient modulation” is indefinite. Specifically, “is capable of ... modulation ” is indefinite because it is unclear whether or not it modulates. Also, the phrase “more efficient modulation” is indefinite because it is not known what type of modulation is intended and hence what is encompassed by the phrase, and it is not known how efficiency is measured. Appropriate clarification is required.

At Claim 2, line 2, the phrase “corresponds to” is indefinite. It is not clear how the sequence “corresponds to” the locus. It is suggested that the phrase be changed to --is located at--. Further, it is unclear how the “sequences” at line 3 relate to the “nucleic acid molecule” at line 1. They appear to be one in the same. Appropriate correction is required to clarify the claimed invention.

At Claim 2, line 3, the phrase “control production” is indefinite. It is not clear what is encompassed by “control,” and how the nucleic acid sequences control flavonoid production.

Appropriate correction is required to clarify the metes and bounds of the claimed invention.

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At Claims 3-13, line 2, "complementary nucleotide sequence ... as set forth in SEQ ID NO:1" does not make sense because SEQ ID NO:1 is the coding sequence.

At Claims 3-13, line 2, the term "substantially" is a relative term, and hence it is not known what is encompassed by the claim. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claims 3-13, line 3, the term "similarity" is unclear in the present context. Nucleic acid sequences are being compared, which can be compared only in terms of --identity--.

At Claims 3-13, line 3, the phrase "capable of hybridizing" is indefinite because it is unclear whether or not it hybridizes. The phrase should be changed to --which hybridizes--.

At Claims 3-13, line 4, the phrase "low stringency conditions" is indefinite. Applicant has not defined the conditions in terms of hybridization and wash conditions, *e.g.* salt concentration, temperature, time, and hence the phrase is indefinite.

At Claims 14-24, line 3, the term "substantially" is a relative term, and hence it is not known what is encompassed by the claim. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claim 26, lines 2-3, "a nucleotide selected from..." is improper Markush language. Also, the multiple use of "or" at lines 5 (one occurrence) and 7 (two occurrences) renders the Markush language improper. The alternatives should be included as additional Markush members. Finally, "and/or" at line 10 renders the claim indefinite and should be changed to --or--.

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At Claim 26, line 4, "an amino acid sequence" should be --the amino acid sequence-- as it refers to specific sequences.

At Claim 26, lines 4-5, "one of SEQ ID NO:2, 4, 6, 8, 10, 11, 12, 13, 15, 17, 19, 21, 23, or 25" should be --any one of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, SEQ ID NO:21, SEQ ID NO:23, or SEQ ID NO:25--.

At Claim 26, line 6, "a nucleotide sequence" should be changed to --the nucleotide sequence" as it refers to specific sequences.

At Claim 26, lines 6-7, "one of SEQ ID NO:1, 3, 5, 7, 14, 16, 18, 20, 22 or 24" should be --any one of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22 or SEQ ID NO:24--.

At Claim 26, line 9, the phrase "capable of hybridizing" is indefinite because it is unclear whether or not it hybridizes. The phrase should be changed to --which hybridizes--.

At Claim 26, line 9, the phrase "low stringency conditions" is indefinite. Applicant has not defined the conditions in terms of hybridization and wash conditions, *e.g.* salt concentration, temperature, time, and hence the phrase is indefinite.

At Claim 27, line 1, the phrase "capable of synthesizing" is indefinite because it is unclear whether or not it synthesizes. The phrase should be changed to --which synthesizes--.

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At Claim 27, line 2, the phrase “funtional derivative” is indefinite. There are many different types of derivatives, and it is unclear what is encompassed by the phrase. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claim 27, line 3, “suitable” is a meaningless term, as Applicant has not defined how suitability is determined. The term should be deleted.

At Claim 27, line 3, “nucleic acid molecule” lacks an article.

At Claim 27, lines 4-5, the phrase “under conditions permitting the eventual expression of said nucleic acid molecule” is a meaningless phrase because Applicant has not defined the appropriate conditions. The phrase should be changed to --wherein the nucleic acid molecule is expressed--.

At Claim 27, line 5, before “regenerating” --and-- should be inserted.

At Claim 27, lines 6-7, the phrase “for a time and under conditions sufficient to permit the expression of the nucleic acid molecule” is a meaningless phrase because Applicant has not defined the appropriate time and conditions. The phrase should be changed to --wherein the nucleic acid molecule is expressed--.

At Claim 28, line 2, the term “existing” is indefinite, and it is unclear how it differs from “endogenous.”

At Claim 28, line 3, “suitable” is a meaningless term, as Applicant has not defined how suitability is determined. The term should be deleted.

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At Claim 28, line 4, the term “derivative” is indefinite. There are many different types of derivatives, and it is unclear what is encompassed by the term. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claim 28, the phrase “where necessary” is meaningless because Applicant has not defined when and how necessity is determined. The phrase should be deleted.

At Claim 28, lines 6-7, the phrase “under conditions sufficient to permit the expression of the nucleic acid molecule” is a meaningless phrase because Applicant has not defined the appropriate conditions. The phrase should be changed to --wherein the nucleic acid molecule is expressed--.

At Claim 29, line 1, “the introduced nucleic acid molecule” lacks proper antecedent basis.

At Claim 29, line 2, “a nucleotide sequence or complementary nucleotide sequence selected from...” is improper Markush language. Also, the multiple use of “or” at lines 4 (one occurrence) and 6 (two occurrences) renders the Markush language improper. The alternatives should be included as additional Markush members. Finally, “and/or” at line 9 renders the claim indefinite and should be changed to --or--.

At Claim 29, line 3, “an amino acid sequence” should be --the amino acid sequence-- as it refers to specific sequences.

At Claim 29, lines 3-4, “one of SEQ ID NO:2, 4, 6, 8, 10, 11, 12, 13, 15, 17, 19, 21, 23, or 25” should be --any one of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, SEQ ID NO:21, SEQ ID NO:23, or SEQ ID NO:25--.

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At Claim 29, line 5, "a nucleotide sequence" should be changed to --the nucleotide sequence" as it refers to specific sequences.

At Claim 29, lines 5-6, "one of SEQ ID NO:1, 3, 5, 7, 14, 16, 18, 20, 22 or 24" should be --any one of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22 or SEQ ID NO:24--.

At Claim 29, line 8, the phrase "capable of hybridizing" is indefinite because it is unclear whether or not it hybridizes. The phrase should be changed to --which hybridizes--.

At Claim 26, line 8, the phrase "low stringency conditions" is indefinite. Applicant has not defined the conditions in terms of hybridization and wash conditions, *e.g.* salt concentration, temperature, time, and hence the phrase is indefinite.

At Claim 30, line 1, "the recipient plant" lacks proper antecedent basis.

At Claim 30, line 1, "plant is selected from..." is improper Markush language.

At Claim 31, line 1, the phrase "capable of modulating" is indefinite because it is unclear whether or not it modulates, and how it modulates. Appropriate correction is required to clarify the claimed invention.

At Claim 31, line 3, "suitable" is a meaningless term, as Applicant has not defined how suitability is determined. The term should be deleted.

At Claim 31, line 4, the term "derivative" is indefinite. There are many different types of derivatives, and it is unclear what is encompassed by the term. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

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At Claim 31, line 5, "said cell or cells" lacks proper antecedent basis.

At Claim 32, line 2, "a nucleotide selected from..." is improper Markush language. Also, the multiple use of "or" at lines 4 (one occurrence) and 6 (two occurrences) renders the Markush language improper. The alternatives should be included as additional Markush members. Finally, "and/or" at line 9 renders the claim indefinite and should be changed to --or--.

At Claim 32, line 3, "an amino acid sequence" should be --the amino acid sequence-- as it refers to specific sequences.

At Claim 32, lines 3-4, "one of SEQ ID NO:2, 4, 6, 8, 10, 11, 12, 13, 15, 17, 19, 21, 23, or 25" should be --any one of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, SEQ ID NO:21, SEQ ID NO:23, or SEQ ID NO:25--.

At Claim 32, line 5, "a nucleotide sequence" should be changed to --the nucleotide sequence" as it refers to specific sequences.

At Claim 32, lines 5-6, "one of SEQ ID NO:1, 3, 5, 7, 14, 16, 18, 20, 22 or 24" should be --any one of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22 or SEQ ID NO:24--.

At Claim 32, line 8, the phrase "capable of hybridizing" is indefinite because it is unclear whether or not it hybridizes. The phrase should be changed to --which hybridizes--.

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At Claim 32, line 8, the phrase "low stringency conditions" is indefinite. Applicant has not defined the conditions in terms of hybridization and wash conditions, *e.g.* salt concentration, temperature, time, and hence the phrase is indefinite.

At Claim 33, line 2, "a sequence of nucleotides selected from..." is improper Markush language. Also, the multiple use of "or" at lines 4 (one occurrence) and 6 (two occurrences) renders the Markush language improper. The alternatives should be included as additional Markush members. Finally, "and/or" at line 9 renders the claim indefinite and should be changed to --or--.

At Claim 33, line 3, "an amino acid sequence" should be --the amino acid sequence-- as it refers to specific sequences.

At Claim 33, lines 3-4, "one of SEQ ID NO:2, 4, 6, 8, 10, 11, 12, 13, 15, 17, 19, 21, 23, or 25" should be --any one of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, SEQ ID NO:21, SEQ ID NO:23, or SEQ ID NO:25--.

At Claim 33, line 5, "a nucleotide sequence" should be changed to --the nucleotide sequence" as it refers to specific sequences.

At Claim 33, lines 5-6, "one of SEQ ID NO:1, 3, 5, 7, 14, 16, 18, 20, 22 or 24" should be --any one of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22 or SEQ ID NO:24--.

At Claim 33, line 8, the phrase "capable of hybridizing" is indefinite because it is unclear whether or not it hybridizes. The phrase should be changed to --which hybridizes--.

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At Claim 33, line 8, the phrase "low stringency conditions" is indefinite. Applicant has not defined the conditions in terms of hybridization and wash conditions, *e.g.* salt concentration, temperature, time, and hence the phrase is indefinite.

Claims 38 and 39 are incomplete for omitting essential steps. See MPEP § 2172.01.

At Claim 38, line 2, the term "modulating" is indefinite. There are many different types of modulation, and hence it is not known what is encompassed by the term. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claim 39, line 1, "the nucleotide sequence" lacks proper antecedent basis.

At Claim 39, line 1, "nucleotide sequence is selected from..." is improper Markush language. Also, the multiple use of "or" at lines 3 (one occurrence) and 5 (two occurrences) renders the Markush language improper. The alternatives should be included as additional Markush members. Finally, "and/or" at line 8 renders the claim indefinite and should be changed to --or--.

At Claim 39, line 2, "an amino acid sequence" should be --the amino acid sequence-- as it refers to specific sequences.

At Claim 39, lines 2-3, "one of SEQ ID NO:2, 4, 6, 8, 10, 11, 12, 13, 15, 17, 19, 21, 23, or 25" should be --any one of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, SEQ ID NO:21, SEQ ID NO:23, or SEQ ID NO:25--.

~~At Claim 39, line 4, "a nucleotide sequence" should be changed to --the nucleotide sequence~~
as it refers to specific sequences.

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At Claim 39, lines 4-5, "one of SEQ ID NO:1, 3, 5, 7, 14, 16, 18, 20, 22 or 24" should be --any one of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22 or SEQ ID NO:24--.

At Claim 39, line 7, the phrase "capable of hybridizing" is indefinite because it is unclear whether or not it hybridizes. The phrase should be changed to --which hybridizes--.

At Claim 39, line 7, the phrase "low stringency conditions" is indefinite. Applicant has not defined the conditions in terms of hybridization and wash conditions, *e.g.* salt concentration, temperature, time, and hence the phrase is indefinite.

Claim Rejections - 35 USC § 101

15. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

16. Claims 38 and 39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a "use" which is not one of the five classes of statutory subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: — — — — —

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-24, and 26-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Holton *et al.* (WO 93/20206).

The claims are indefinite for the reasons discussed above. In particular, “derivative,” “more efficient modulation of hydroxylation” and “low stringency conditions” are all indefinite.

Holton discloses isolated nucleic acid molecules from petunia, rose, and chrysanthemum which encode F3'H, as well as derivatives of said nucleic acid molecules (p. 32-37). The isolated nucleic acid molecules of Holton are derivatives, have at least 60% similarity, or would hybridize under low stringency conditions to the disclosed nucleic acid molecules of the instant invention of SEQ ID NO:1, 3, 5, 7, 9, 14, 16, 18, 20, 22, and 24. Additionally, in view of the indefiniteness of the claim language “more efficient modulation of hydroxylation,” and Applicant’s failure to clearly distinguish the nucleic acid molecules of the instant invention from those of the prior art reference in terms of enzyme activity of the encoded proteins, Examiner submits that the claimed nucleic acid molecules of the instant invention are anticipated by the prior art reference. Further, Holton teaches vectors and transgenic plants comprising the disclosed nucleic acid molecules, and methods of altering F3'H activity and altering flowering flower color in transgenic plants by transformation with the disclosed nucleic acid molecules (p. 33-34, 36-37). Hence, all of the claim limitations are previously disclosed by Holton.

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19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the Group receptionist whose telephone number is (703) 308-1234.

A handwritten signature in black ink that reads "Amy Nelson". The signature is written in a cursive, flowing style.

AMY J. NELSON, PH.D
PRIMARY EXAMINER

Amy J. Nelson, Ph.D.

November 2, 2000
